

38. (Withdrawn) The method of claim 37 wherein said step d'') comprises heating said mixture under reflux with stirring.

39. (Withdrawn) The method of claim 37 wherein said step e'') comprises cooling the solution to room temperature.

40. (Withdrawn) The method of claim 39 wherein said step e'') comprises stirring the solution at room temperature for 24 hours.

41. (Withdrawn) The method of claim 37 wherein drying step f'') takes place in an oven.

42. (Withdrawn) The method of claim 37, wherein the crude Form is lercanidipine hydrochloride crude Form (A), lercanidipine hydrochloride crude Form (B) or lercanidipine crude Form (C).

43-50. (Cancelled)

51. (Withdrawn) A method of producing lercanidipine hydrochloride crystalline Form (II), which has an X-ray diffraction pattern, at wavelength λ , as shown in Figure 12, which comprises:

d''') adding ethanol or isopropanol with a water content below 10% by weight to lercanidipine hydrochloride and refluxing to produce a solution;

e''') cooling the solution and stirring until the concentration of lercanidipine hydrochloride dissolved in the crystallization solvent is 2%; and

f''') recovering the solid produced in step e''') to produce lercanidipine hydrochloride Form (II).

52. (Withdrawn) The method of claim 51 wherein ethanol is added in said step d''').

53. (Withdrawn) The method of claims 51 wherein the water content of the solvent in step d''') is between 5 and 10%.

61. (Withdrawn) The method of claim 56, wherein the aprotic dipolar solvent is N-methylpyrrolidone.

62. (Withdrawn) The method of claim 56, wherein the temperature of said step d''') is between 20 and 70°C.

63. (Withdrawn) The method of claim 56, wherein stirring in said step e''') takes place at a temperature between 20 and 25°C.

64. (Withdrawn) The method of claim 56, wherein drying in said step f''') takes place at 70°C.

65. (Withdrawn) An antihypertensive pharmaceutical composition comprising (1) a predetermined content of lercanidipine hydrochloride crystalline Form (II) or a combination of lercanidipine hydrochloride crystalline Form (I) and lercanidipine hydrochloride crystalline Form (II) comprising a predetermined content of each crystalline form, and (2) at least one component selected from the group consisting of a pharmaceutically acceptable carrier or diluent, a flavorant, a sweetener, a preservative, a dye, a binder, a suspending agent, a dispersing agent, a colorant, a disintegrant, an excipient, a lubricant, a plasticizer, and an edible oil.

66. (Withdrawn) A unit dosage form comprising the antihypertensive pharmaceutical composition of claim 65.

67. (Withdrawn) The unit dosage form of claim 66 wherein the dosage form is a lercanidipine immediate release dosage form.

68. (Withdrawn) The unit dosage form of claim 66 wherein the dosage form is a lercanidipine controlled release dosage form.

69. (Withdrawn) The unit dosage form of claim 66 wherein the dosage form comprises a lercanidipine immediate release phase and a lercanidipine controlled release phase.

70. (Withdrawn) The unit dosage form of claim 66, wherein the composition comprises 0.1 to 400 mg lercanidipine hydrochloride.

71. (Withdrawn) The unit dosage form of claim 70, wherein the composition comprises 1 to 200 mg lercanidipine hydrochloride.

72. (Withdrawn) The unit dosage form of claim 71, wherein the composition comprises 5 to 40 mg lercanidipine hydrochloride.

73. (Withdrawn) A method of treating a subject with hypertension, coronary heart disease or congestive heart failure the method comprising administering a therapeutically effective amount of lercanidipine hydrochloride crystalline Form (II) or a combination of lercanidipine hydrochloride crystalline Forms (I) and (II) having a predetermined content in each of said Form I and II to a subject in need of such treatment.

74. (Withdrawn) A method of treating or preventing atherosclerotic lesions in arteries in a subject, which comprises administering a therapeutically effective amount of lercanidipine hydrochloride crystalline Form (II) or a combination of lercanidipine hydrochloride crystalline Forms (I) and (II) having a predetermined content in each of said Form I and II to a subject in need of such treatment.

75. (Withdrawn) A method of treating or preventing heart failure in a subject, which comprises administering a therapeutically effective amount of lercanidipine hydrochloride crystalline Form (II) or a combination of lercanidipine hydrochloride crystalline Forms (I) and (II) having a predetermined content in each of said Form I and II to a subject in need of such treatment.

76. (Withdrawn) The method of any one of claims 73 - 75 wherein said subject in need is a mammal.

77. (Withdrawn) The method of claim 76 wherein said subject is a human.

78. (Withdrawn) An antihypertensive composition comprising predetermined amounts of lercanidipine hydrochloride crystalline Form (I) and lercanidipine hydrochloride crystalline Form (II).

79. (Withdrawn) The antihypertensive composition of claim 78 wherein the lercanidipine hydrochloride crystalline Form (I) has a melting point of about 197-201°C and the lercanidipine hydrochloride crystalline Form (II) has a melting point of about 207-211°C, when said melting points are determined as DSC peaks.

80. (Withdrawn) The antihypertensive composition of claim 78 or claim 79 wherein the ratio of Form (I) : Form (II) is between 1:9 to 9:1.

81. (Withdrawn) The antihypertensive composition of claim 78 wherein the ratio of Form (I) : Form (II) is selected from the group consisting of 9:1, 7:3, 1:1, 3:7 and 1:9.

82. (Previously presented) The isolated lercanidipine crystal Form of claim 27 or 28 comprising an average particle size of D (50%) 2-8 μm and D (90%) < 15 μm .

83. (Withdrawn) The antihypertensive pharmaceutical composition of claim 65 wherein said lercanidipine hydrochloride crystalline Forms (I) and (II) each have an average particle size of D (50%) 2-8 μm and D (90%) < 15 μm .

84. (Withdrawn) The antihypertensive composition of claim 78 wherein said lercanidipine crystalline Forms (I) and (II) each have an average particle size of D (50%) 2-8 μm and D (90%) < 15 μm .

85. (Previously presented) A lercanidipine hydrochloride of crystalline Form II exhibiting essentially the following X-ray diffraction data:

D (Å)	Relative Intensity
-------	--------------------

	(I/I ₀)
9.3	35
6.0	45
5.49	65
4.65	52
4.27	74
3.81	41
3.77	100
3.58	44
3.54	29

86. (Previously presented) A lercanidipine hydrochloride crystalline polymorphic form (Form II) having a melting point determined by differential scan calorimetry of 207-211°C.

87. (Previously presented) A lercanidipine hydrochloride crystalline polymorphic form (Form II) having the Infrared spectrum (IR) as a KBr powder which shows absorption bands at 3183, 2684, 1705, 1675, 1526, 1350, 1402 and 1380 cm⁻¹.

88. (Previously presented) A lercanidipine hydrochloride crystalline polymorphic form (Form II) having a ¹³C-NMR solid phase spectrum which exhibits peaks at δ168.1, 166.6, 151.9, 121.9, 104.0, 102.8, 79.0, 66.0, 58.0, 49.7, 48.8, 44.3, 40.5, 29.8, 27.6, 23.5, 19.6 and 18.3 ppm.

89. (Previously presented) A composition comprising lercanidipine hydrochloride wherein at least 90% of its lercanidipine hydrochloride content is Form II.

90. (Previously presented) The composition of claim 89 wherein the composition is a pharmaceutical composition.

91. (Previously presented) The composition of claim 90 comprising from about 5 to about 40 mg of lercanidipine hydrochloride Form II.

92. (Withdrawn) A pharmaceutical formulation comprising lercanidipine hydrochloride Form II which has at least one of the following pharmacokinetic profile feature when administered to a human as a 10 mg tablet; an AUC_{0-t} (ng. h/ml) of about 10.36; a C_{max} (ng/ml) of about 3.22; and a t_{max} of about 2.50.